

EXHIBIT B

McDowell, Amanda

From: Daw, Alison (USACAN) <Alison.Daw@usdoj.gov>
Sent: Friday, October 4, 2019 1:44 PM
To: Cazares, Steve; Coopersmith, Jeffrey; McDowell, Amanda; Wade, Lance; Downey, Kevin; Looby, Patrick; Bostic, John (USACAN)
Cc: MartinezResly, Jaclyn; Norton, Marci
Subject: FDA -- Update re compliance with court order in US v. Holmes and Balwani
Attachments: FDA list of custodians searched.pdf

[EXTERNAL]

The FDA is providing the information herein as part of the meet and confer process in response to the Court's recent order (ECF 134). It is intended to provide the parties with additional insight into the agency's production. It is not intended to waive the attorney-client or work product privileges of the FDA or HHS, its parent agency.

Once you have had an opportunity to consider this information, please identify what issues, if any, you believe remain to be resolved concerning the FDA's production.

Attached to this email is FDA's list of custodians. Other than the specific technical issues identified by the FDA in its 9-23-19 letter to Mr. Bostic, including corrupt PST and backup tape issues and the documents identified as containing foreign language, the FDA has now produced all of the responsive, non-privileged, non-duplicative documents responsive to the Court's order for the custodians on the attached list. The FDA has initiated a search for responsive documents from the files of an additional custodian, Katie Serrano, and will produce the responsive, non-privileged, non-duplicative documents responsive to the Court's order on the motion to compel as soon as possible.

The FDA began the process of responding to the subpoena well before the Court issued its order. Because the FDA had no document processing software at that time, they undertook collection and review manually. The custodians who are current FDA employees were provided with the subpoena and instructed to search for responsive documents. If they were unable to comply, an electronic search was conducted using the following terms: **Balwani OR "Elizabeth w/3 Holmes" OR eholmes OR eholmes2003 OR eholmes@theranos.com OR Theranos OR "TSPU" OR "TSCD" OR Nanotainer OR "Capillary Tubes" OR "Nanotainer Tubes" OR "Lithium-Heparin" OR "CTN" OR "K2EDTA" OR "K152647" OR "K152965" OR "K152971" OR "Q151162" OR "Q151964" OR "Q160388" OR "Q160470" OR "K143236" OR "CW150009" OR "TLAS"**

These terms were also used to search the records of custodians who were no longer with the FDA. The FDA then reviewed the documents manually, one-by-one, to identify those responsive to the subpoena.

Once the FDA obtained access to Relativity through its parent agency, it used the search terms below to identify, from among all documents collected in response to the subpoena from the listed custodians, the subset of documents the FDA is required to produce pursuant to the Court's order.

Category Search phrases

Category Theranos* AND (John.Carreyrou@dowjones.com OR

1 dowjones.com OR WSJ OR "Wall Street Journal" "212-416-2309" OR "917-536-7824" OR Carreyrou)

Category (Theranos* AND ("Clinical Laboratory Improvement Amendments" OR CLIA) AND compl*)
 2 AND NOT Waiver

Theranos* AND (“Clinical Laboratory Improvement Amendments” OR CLIA) and Survey

Category 3 Theranos* AND (“American Association of Clinical Chemistry” OR AACC OR “Associated Regional and University Pathologists” OR ARUP OR Mayo OR Hopkins OR LabCorp OR Quest, OR “American Clinical Lab Association” OR ACLA OR “clinical laboratory” OR “clinical lab”)

Category 4 Theranos* AND (Clearance OR PMA OR “premarket approval” OR “De novo” or “Humanitarian Device Exemption” OR HDE OR “510(k)” OR “510k” OR “Investigational device exemption” or IDE OR "K152647" OR "K152965" OR "K152971" OR "Q151162" OR "Q151964" OR "Q160388" OR "Q160470" OR "K143236" OR "CW150009")

Category 5 Theranos* AND ((302 and FBI) OR ROI OR “Record of Investigation” OR “Report of Interview” OR “Memorandum of Interview” OR MOI OR OCI OR “office of criminal investigations” OR “special agent”)

Category 6 N/A: Included in 2.

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FDA'S LIST OF CUSTODIANS

| | | | |
|-------------------------|------|------------------------|------|
| Alberto Gutierrez | CDRH | Tamara Feldblyum | CDRH |
| Ann Sullivan | CDRH | Uwe Scherf | CDRH |
| Cara Tenenbaum | CDRH | Yung Chan | CDRH |
| Catherine Bahr | CDRH | Yvonne Shea | CDRH |
| Courtney Lias | CDRH | Eric Flamm | OC |
| Elizabeth Hillebrenner | CDRH | Lisa Dwyer | OC |
| Erica Takai | CDRH | Margaret Hamburg | OC |
| Eveline Arnold | CDRH | Ariel Seeley | OCC |
| Haja Sittana El Mubarak | CDRH | Claudia Zuckerman | OCC |
| Ian Pilcher | CDRH | David Mednick | OCC |
| Ileana Elder | CDRH | Elizabeth Dickinson | OCC |
| James Kolonay | CDRH | Ian Pearson | OCC |
| Jeff Shuren | CDRH | Jim Smith | OCC |
| Jonette Foy | CDRH | Laura Bailis | OCC |
| Juliane Lessard | CDRH | Marcy Busch | OCC |
| Kelly Kelm | CDRH | Ruey Ju | OCC |
| Kelly Wilkicki | CDRH | Sara Beardsley | OCC |
| Kim Sapsford-Medintz | CDRH | Siyeon Lee | OCC |
| Kylie Haskins | CDRH | Vince Amatrudo | OCC |
| Lauren Silvis | CDRH | Wendy Vicente | OCC |
| Leroy Hwang | CDRH | Caitlin Pennington | OL |
| Leslie Landree | CDRH | Jennifer Tomasello | OL |
| Li Li | CDRH | Eric Pahon | OMA |
| Lindsay Lloyd | CDRH | Jennifer Dooren | OMA |
| Marisa Cruz | CDRH | Stephanie Caccomo | OMA |
| Mayra Garcia | CDRH | Inspection Record File | ORA |
| Nancy Pressley | CDRH | Mary Hole | ORA |
| Nisar Pampori | CDRH | Seema Singh | ORA |
| Olga Claudio | CDRH | Sergio Chavez | ORA |
| Pamela Scott | CDRH | | |
| Peyton Hobson | CDRH | | |
| Ryan Lubert | CDRH | | |
| Sally Hojvat | CDRH | | |
| Scott McFarland | CDRH | | |
| Silke Schlottmann | CDRH | | |
| Sonja Fulmer | CDRH | | |
| Stacye Beck | CDRH | | |
| Stephen Lovell | CDRH | | |